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In re Application of	:
SZPIRER ET AL.	:Decision on Petition
Serial No.: 10/507,923	:
Filed : July 19, 2005	:
Attorney Docket No.: VANM290.001APC	:

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on June 10, 2008 requesting review of a lack of unity determination. The decision mailed on 30 March 2009 is vacated because it contained 3 pages that did not belong in the decision.

BACKGROUND

This application was filed as a national stage application under 35 USC 371 of PCT/BE03/00045 and as such, is eligible for unity of invention practice.

In a written lack of unity determination mailed March 29, 2007, the examiner divided claims 15-33 into three groups as follows:

> Group I, claims 15-24, and 26-28, drawn to a recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule and ii) a genetic sequence encoding an antidote molecule to said toxic molecule.
>
> Group II, claims 15-28, drawn to a recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule, ii) a genetic sequence encoding an antidote molecule to said toxic molecule and iii) a genetic sequence which is the target of the toxic molecule.

Group III, claims 29-33 drawn to a method of producing and selecting a genetically modified cell or organism.

The examiner then requested that applicants select particular species depending on which group was selected. The examiner provided a prior art reference to support this determination for lack of unity.

On September 24, 2007, applicants elected Group I without traverse, claims 15-24, 26-28, and "does not comprise a selectable marker," "wherein the genetic sequence encoding the antidote is not added to the construct," "ccdB," "yeast cell," "an exogenous compound," "chloroplast," and "two different toxic genes" all with traverse.

In the first Office action of the merits mailed December 12, 2007, the examiner considered the traversal and made the unity of invention determination FINAL. Claims 15, 16, 18, 22-24, 26-27, 35 were examined. Claims 15-16, 18, 22-24, 26-27, 35 were rejected under 35 USC 101, 35 USC 112/1st paragraph written description, 35 USC 112/1st paragraph enablement, 35 USC 112/2nd paragraph, 35 USC 102(a), 35 USC 102(e) and 35 USC 103(a).

A response to the Office action was filed on June 10, 2008 which included amendments to the claims, a response and this petition requesting reconsideration under 37 C.F.R 1.144 of the lack of unity requirement.

DISCUSSION

Applicants' petition filed June 10, 2008 and the file history have been considered carefully. Applicants traverse the restriction of the non-elected embodiments of the invention and request rejoinder of withdrawn dependent claims 34-40.

At the onset, a few irregularities are noted in the original lack of unity of invention determination.

In this application, the examiner determined that unity of invention was lacking determination between Group I and II as follows:

Group I, claims 15-24, and 26-28, drawn to a recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule and ii) a genetic sequence encoding an antidote molecule to said toxic molecule.

Group II, claims 15-28, drawn to a recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule, ii) a genetic sequence encoding an antidote molecule to said toxic molecule and iii) a genetic sequence which is the target of the toxic molecule.

As set forth in the PCT International search and preliminary examination guidelines, paragraph 10.03 provides that

> Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims.

Group I can be characterized as A + X. Group II can be characterized as A + X + Y. In this claim set, there is no claim corresponding to A + Z, for example, which would permit a lack of unity determination a priori. Moreover, while Group II requires the technical feature of "Y" which is not required for Group I, there is nothing required by Group I which is also not encompassed by Group II. Group I and Group II both require a common technical feature of "a recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule and ii) a genetic sequence encoding an antidote molecule to said toxic molecule." As such, unity of invention is present between Group I and Group II.

Concerning the election of species requirements, it is noted that several of the requirements did not set forth clearly delineated species amongst which to elect and that the rationale for requiring the election of species did not use the appropriate form paragraph.

The requirement to "elect one of the alternative genetic constructs in claim 15(i) that does not does not comprise a selectable marker" is problematic. The examiner characterized the election as "wherein the genetic construct does not comprise a selectable marker as recited in claim 15(i). Such a negative limitation does not appear in claim 15(i). Moreover, Claim 15(i) does not recite a list of alternative genetic constructs. Claim 15(i) is generic to genetic constructs. For this reason, the election of species requirement to elect a construct that does not does not comprise a selectable marker is improper.

For similar reasons, the requirement to "elect one of the alternative constructs of claim 15(ii) wherein the construct that encodes an antidote" is improper.

Applicant was required to elect a biological organism from the groups of organism of plant, animal, mammal, insect or yeast. Because insects and mammals are both subsets of the genus of animals, this election of species requirement is improper and has been reformatted as a requirement to elect a plant, animal or yeast.

The following election of species requirements are maintained for the following reasons:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The requirement to elect one of the toxic molecules as set forth in original claim 18.

The requirement to elect one of genetic sequences that is the target of the toxic molecule as set forth in original claim 25.

The requirement to elect between an exogenous compound or a compound which is synthesized by the host cell of original claim 24.

The requirement to elect one of the host cell compartments as set forth in original claims 26-27.

The requirement to elect whether the selectable marker is bordered by two different or identical toxic genes as set forth in original claims 28.

Within each group of species listed above, the species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the species lack unity of invention because even though the inventions of these groups require the technical feature of "recombinant cell or organism having incorporated into the genome i) a genetic construct a nucleotide sequence encoding a toxic molecule and ii) a genetic sequence encoding an antidote molecule to said toxic molecule" this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of the prior art rejections of record.

Turning now to the merits of the petition, applicants argue that all the groups require a technical feature that makes a contribution over the art. This position is not persuasive in view of the outstanding prior art rejections on the elected invention.

Rejoinder Opportunities:

The examiner has restricted between product (Group I/II) and process (Group III) and has required an election of species in this national stage filing of a PCT. It is noted that in both of these situations, rejoinder practice applies. See MPEP 1893.03(d) states in part:

> If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04. Any nonelected processes of making and/or using an allowable product should be considered for rejoinder. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product.

At this time, there is no special technical feature which makes a contribution over the prior art to link Groups (I and II) with Group III. Moreover the generic claims that encompass the species

are not yet in condition for allowance. For these reasons, it is premature to consider rejoinder of the method of Group III or the examination of additional species.

DECISION

Accordingly, the petition filed under 37 CFR 1.144 is **GRANTED-IN-PART**.

The restriction requirement is withdrawn between elected Group I and non-elected Group II.

The restriction requirement is maintained between elected Group I/II and non-elected Group III.

The election of species requirement is maintained as follows:

> The requirement to elect one of the toxic molecules as set forth in original claim 18 is maintained. Applicants elected ccdB.
>
> The requirement to elect between an exogenous compound or a compound which is synthesized by the host cell as set forth in original claim 24 is maintained. Applicants elected the exogenous compound.
>
> The requirement to elect one of the host cell compartments as set forth in original claims 26-27 is maintained. Applicants elected the chloroplast.
>
> The requirement to elect whether the selectable marker is bordered by two different or identical toxic genes as set forth in original claims 28 is maintained. Applicants elected a selectable marker which is bordered by two different toxic genes.
>
> The requirement to elect a biological organism from the groups of organism of plant, animal, mammal, insect or yeast has been reformatted as a requirement to elect a plant, animal or yeast. Applicants elected the yeast cell.

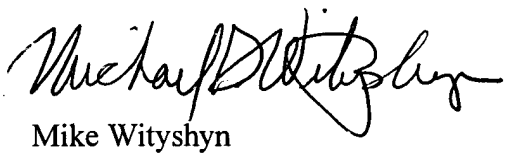
All other election of species requirements have been withdrawn for the reasons set forth in the discussion section of this decision.

The application will be forwarded to the examiner to consider the papers filed 10 June 2008 and to prepare an Office action addressing the claims of Groups I and II consistent with this petition decision.

Should all claims drawn to the elected invention become in condition for allowance, the examiner will consider claims directed to additional species and non-elected process in keeping with the guidance of MPEP 1893.05(d) and 821.04.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Quality Assurance Specialist Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.



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